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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/751,654

Applicant(s)

BAVYKIN ET AL.

Examiner

Suryaprabha Chunduru

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1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8,11,13 and 14 is/are rejected.
- 7) ☒ Claim(s) 2,5-7,9,10,12 and 15-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other \_\_\_\_\_

**DETAILED ACTION**

1. Preliminary Amendment (Paper No. 7) filed on June 18, 2001 has been entered.
2. The disclosure is objected because of the following informalities:

***Drawings***

- a. The drawings are objected because: (i) the brief description of the drawings on page 4 does not describe panels A-C in FIG.1, A-C in FIG.2, A-B in FIG.3, A-G in FIG. 4.  
(ii) FIG. 5 is not described. Correction is required.
- b. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs in Fig. 4 will be accepted if the conditions for accepting color drawings have been satisfied.

***Oath/Declaration***

- a. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required.  
See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

(i) one of the inventor's residence address and citizenship information is missing.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 8 are vague and unclear for being reciting the term "manipulating" genetic material, because it is unclear what it accomplishes for. The method steps recite isolation or extraction of genetic material but not manipulate genetic material by recombinant techniques.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 8, 11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henco et al. (USPN. 5,652,141) and in view of Eldadah et al. (Nucleic Acids Research, 24(20): 4092-4093).

Henco et al. teach a process for isolating nucleic acids wherein Henco et al. disclose that the method comprises nucleic acids (genetic material) immobilized on to silica gel matrix by subjecting cells to lyse (disrupt) to release genetic material on to the silica matrix and subsequently elute the genetic material from the silica column (see column 2, lines 13-45, column 5, claim 1). Henco et al. also disclose that impurities (cell detritus) were washed out using wash buffers ( see column 4, line 67 and column 5, lines 1-11, claim 8); the silica gel device is subjected to pressure or centrifugation to allow the lysate to pass through the device (see column 4, lines 54-65). However, Henco et al. did not disclose labeling the nucleic acids.

Eldadah et al. teach a method for isolation and detection of DNA wherein Eldadah et al. disclose the labeling of DNA fragments (see page 4092, paragraphs 2-3). Further Eldadah et al. disclose that the lysis and wash buffer includes guanidine salts and EDTA respectively. (see page 4092, paragraph 4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of isolating nucleic acids as taught by Henco et al. with the method of Eldadah et al. which is applicable to achieve rapid identification of nucleic acids because Henco et al. states that 'the current nucleic acid isolation techniques are capable of being automatized, but are costly and are not suitable for samples in large series'. One form of

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the feasibility, expressly motivated by Eldadah et al. is the use of labeling device to "to provide a sensitive and rapid isolation of DNA". An ordinary practitioner would have been motivated to combine the method of Henco et al. with the labeling method of Eldadah et al. in order to achieve the expected advantage of rapid isolation of nucleic acids.

5. Claims 2, 5-7, 9-10, 12, 15-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M. Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru  
September 10, 2001

*[Handwritten Signature]*  
KENNETH R. HORLICK  
PRIMARY EXAMINER  
GROUP 1600